510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
#K033491

B. Purpose for Submission:
New device

C. Analyte:
D-Dimer

D. Type of Test:
Quantitative

E. Applicant:
Roche Diagnostics Corporation

F. Proprietary and Established Names:
CARDIAC D-Dimer Assay; Fibrin Split Products, Antigen, antiserum, Control

G. Regulatory Information:

1. Regulation section:
   CFR Section 864.7320 - Fibrin Degradation Products Assay
2. Classification:
   Class II
3. Product Code:
   DAP; GHH
4. Panel:
   Hematology (81)

H. Intended Use:

1. Intended use(s):
   The Roche CARDIAC D-Dimer Assay is intended for the quantitative determination of D-Dimer in anticoagulated venous whole blood with the CARDIAC reader instrument.
2. Indication(s) for use:
   Same as the Intended Use.
3. Special condition for use statement(s):
   N/A
4. Special instrument Requirements:
   Roche Diagnostics Corp. CARDIAC Reader (#K000784)

I. Device Description:

The CARDIAC D-Dimer Assay consists of a test strip in plastic casing, with a well for sample application; viewing window at the detection zone; a lot-specific coding chip for each batch of test strips; and Control, Levels I/II. Testing is initiated by the addition of whole blood to the test strip, where red cells are separated from the plasma. A monoclonal antibody (MAB) sandwich complex is formed and bound to a streptavidin band in the detection zone, where the gold-labelled antibody forms a reddish-purple color signal. That signal is determined by the CARDIAC reader.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   Roche Diagnostics Corp. Tina-quant® D-Dimer Test System
2. Predicate K number(s):
   #K002706
3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Sample anticoagulant	Heparin	Same
Assay type	Quantitative immunoassay that utilizes mouse MAB's	Same
Reagents	Includes buffer	Same
Differences		
Item	**Device**	**Predicate**
Sample type	Heparinized plasma separated from venous whole blood during the test procedure	Pre-prepared citrated or heparinized plasma
Principle	Sandwich assay with color indicator	Turbidometric latex assay
Reagents	Biotinylated and gold-labelled anti-D-Dimer antibody	Latex particles coated with anti-human D-Dimer MAB
Measuring range	0.1 – 4.0 ug/mL	0.15 – 9.0 ug/mL

K. Standard/Guidance Document Referenced (if applicable):

N/A

L. Test Principle:

The Roche CARDIAC D-Dimer Assay is an immunoassay based upon the dual monoclonal antibody (MAB) sandwich principle. It uses a poly-streptavidin-biotin capture system with a gold sol particle label. D-Dimer in the sample combines with the antibodies conjugated to the gold sol particles to form a "sandwich". This, in turn, combines with the poly-streptavidin-biotin, which is immobilized in a line across the result window. The speed and intensity of color formation is related to the concentration of D-Dimer in the sample; and results are determined on the CARDIAC Reader instrument.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

(2) to (3) lots of Levels I/II quality control were run at each site.
Within-run – performed at (4) sites and run X (10) on each analyzer. Level I %CV's ranged 7.8 – 14 %. Level II %CV's ranged 8.0 – 18%.
Day-to-day – performed at (2) sites, over 20 - 36 days on each analyzer. Level I %CV's ranged 12.3 – 14%. Level II %CV's ranged 10.5 – 17.1%.
Acceptance criteria: $\leq 20\%$

b. Linearity/assay reportable range:

0.1 – 4 mg/L, determined from method comparison data.

c. Traceability (controls, calibrators, or method):

Calibrated to the Roche Tina-quant D-Dimer method by using a primal master lot to establish a calibration curve.

d. Detection limit:

0.1 mg/L

e. Analytical specificity:

Various levels of D-Dimer tested for endogenous substances (hematocrit, hemoglobin, bilirubin, lipids, and HAMA); and exogenous substances (biotin, heparin, Vitamin C, aspirin and prescription drugs). Fibrinogen and fragments D, E, X and Y were also tested. Rheumatoid factor was not tested.

f. Assay cut-off:

N/A

2. Comparison studies:
    a. *Method comparison with predicate device:*
    Performed at (6) clinical sites, including (5) point-of-care (POC) sites. Studies were done on patients suspected of thromboembolic venous diseases, peri- or post-OR patients and healthy donors. Three lots of CARDIAC test strips were run against the Tina-quant assay. The following regression data were obtained:

    Lot 1, (6) sites - (N = 464); y = -0.04 + 1.09x; r = 0.89
    Lot 2, (6) sites - (N = 463); y = -0.02 + 1.08x; r = 0.90
    Lot 3, (4) sites - (N = 92); y = -0.02 + 1.30x; r = 0.90

    b. *Matrix comparison:*
    Ammonium and lithium heparins were tested on samples (N = 164) with the CARDIAC and Tina-quant D-Dimer assays. Regression data: y = 0.02 + 1.118x; r = 0.908.

3. Clinical studies:
    a. *Clinical sensitivity:*
    N/A
    b. *Clinical specificity:*
    N/A
    c. *Other clinical supportive data (when a and b are not applicable):*
    N/A

4. Clinical cut-off:
    N/A

5. Expected values/Reference range:
    A normal range study was performed on normal individuals (N = 130), consisting of 93 females and 37 males, ranging in age from 19 - 94 years. The mean value was 0.50 mg/L.

N. Conclusion:

The submitted material in this premarket notification is complete and supports a substantial equivalence decision.